

**Notice of Allowability**

Application No.

10/661,049

Examiner

Delia M. Ramirez

Applicant(s)

CUMMINGS ET AL.

Art Unit

1652

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/20/2007.
2. ☒ The allowed claim(s) is/are 17, 18 and 24-26.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).  
\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.  
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.  
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

## DETAILED ACTION

### *Status of the Application*

Claims 17-18 and 24-26 are pending.

Amendment of claims 17-18 and 24 as submitted in a communication filed on 4/20/2007 is acknowledged.

In a telephone conversation with Mr. Christopher Corbett on 5/2/2007, an agreement was reached to amend claims 17 and 25 to place the application in condition for allowance.

In view of Applicant's amendment of claim 17, which is now limited to polynucleotides encoding human core 1  $\beta$ -galactosyl transferases and polynucleotides encoding (1) the polypeptide of SEQ ID NO: 1 or (2) the polypeptide of SEQ ID NO: 1 lacking the transmembrane domain, the previous 35 USC 112, first paragraph rejections are hereby withdrawn.

### *Examiner's Amendment*

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this Examiner's amendment was given in a telephone interview with Mr. Christopher Corbett on 5/2/2007.
3. Please replace claims 17 and 25 as follows:
  17. An expression system comprising:  
an isolated host cell comprising:  
a first expressible recombinant polynucleotide which encodes a human core 1  $\beta$ -galactosyl transferase; and

a second expressible recombinant polynucleotide which encodes a human core 1  $\beta$ 3-galactosyl transferase specific molecular chaperone for expressing the active form of the human core 1  $\beta$ 3-galactosyl transferase, wherein the second expressible recombinant polynucleotide comprises:

- (A) a polynucleotide having the sequence of SEQ ID NO: 2;
- (B) a polynucleotide encoding the polypeptide of SEQ ID NO: 1; or
- (C) a polynucleotide which differs in nucleotide sequence from the polynucleotides of (A) or (B) in that said polynucleotide lacks a nucleotide sequence which encodes a transmembrane domain wherein the human core 1  $\beta$ 3-galactosyl transferase specific molecular chaperone is soluble.

25. The expression system of claim 17 wherein the host cell further comprises an expressible polynucleotide encoding a peptide or polypeptide requiring post-translational glycosylation to form a core 1 structure.

#### ***Reasons for Allowance***

4. The following is an Examiner's statement of reasons for allowance. Although the prior art, as evidenced by Chen et al. (cited in previous Office actions), discloses a polynucleotide encoding the polypeptide of SEQ ID NO: 2 and human 293 cells transformed with the polynucleotide of Chen et al. which comprise an endogenous nucleic acid encoding a human core 1  $\beta$ 3-galactosyl transferase, neither Chen et al. nor the art, together or in combination, teach or suggest an expression system comprising an isolated host cell wherein said host cell comprises recombinant nucleic acids encoding (1) the polypeptide of SEQ ID NO: 1 and (2) a human core 1  $\beta$ 3-galactosyl transferase. Therefore, claims 17-18 and 24-26

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directed to an expression system comprising an isolated host cell which comprises recombinant nucleic acids encoding the polypeptide of SEQ ID NO: 1 (or the polypeptide of SEQ ID NO: 1 lacking its transmembrane domain) and a human core 1  $\beta$ 3-galactosyl transferase, are allowable over the prior art of record.

***Conclusion***

5. Claims 17-18 and 24-26 are allowed.
6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.  
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.  
Primary Patent Examiner  
Art Unit 1652

DR  
May 9, 2007